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EVALUATION OF ANTIHYPERLIPIDEMIC ACTIVITY OF HERBAL MEDICINE AND ITS COMPARISON WITH ROSUVASTATIN

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ABSTRACT

Background: Antihyperlipidemic drugs have been to decreased serum lipid levels in hyperlipidaemic patients and predisposes the patients to various drug related adverse reactions, along with that there are also chance of development of drug resistance. Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, and Zingiber officinale have shown antihyperlipidemic activity alone whereas effects of combination of these on hyperlipidemia have yet to be assessed.

Objective: To evaluation the antihyperlipidemic activity of herbal medicine and it's comparison with rosuvastatin

Methodology: An open labelled parallel arms clinical trial was conducted at Department of Pharmacology, HCMD, Karachi. Patients ageing between 35–65 years of any gender, having central obesity (waist circumference with ethnicity specific), and deranged lipid profile were included as per calculated sample size (200). The exclusion criteria was lactating and pregnant females, patients with other chronic diseases. Patients were split into two groups 100 patients per group based on their treatment. In Group A, Tab. Telmisartan 80 mg and Tab. Rosuvastatin 10 mg once daily for 12 weeks was prescribed. Patients in Group B were given a 500mg polyherbal capsule containing Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, and Zingiber officinale two times a day for 12 weeks. BMI calculation, Waist/Hip Ratio, Blood pressure (Systolic and Diastolic), Lipid profile (Total Cholesterol, HDL, LDL, TGs), Alanine Transaminase (ALT) and Aspartate aminotransferase (AST) were measured after the intervention. The written informed consent was taken, and the study was approved from IRB of the institute. SPSS version 27 was used to analyze the data.

Results: The mean age of the study participants in group A was 53.96 and group B was 52.42 years ($p = 0.312$). The comparison of systolic and diastolic blood pressure from day 0 to day 90 showed an insignificant difference between the herbal treatment and allopathic medicine treated group. The serum cholesterol (SC), high density lipoprotein (HDL), low density lipoprotein (LDL), and triglycerides (TGD) didn't show significant difference between the groups. The SC, LDL, and TGD levels decreased to normal range and HDL levels increased however the potency of both the treatment methods remains equally potential in managing lipid profile. The BMI and WHR showed a significant decrease in herbal treatment group when compared to allopathic group. ALT and AST also showed significant decrease in herbal treatment group ensuring its safety concerns when compared to conventional therapy.

Conclusion: The combination of Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, and Zingiber officinale showed comparable effects in managing the lipid profile of the patients when compared to rosuvastatin. The herbal combination showed a superior activity in decreasing BMI and waist hip ratio of the patients.

KEYWORDS: Antihyperlipidemic Activity, Herbal Medicine, Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, Zingiber officinal and Rosuvastatin

INTRODUCTION

An elevated lipid profile (i.e., cholesterol, triglyceride, LDL) in the blood stream and reduced HDL-C define the Hyperlipidaemia (1). The condition may occur because of abnormal breakdown of fats that result in increased production of lipoproteins or abnormalities in different stages of their dilapidation. Most of the body tissues have lipids which are predominantly deposited under the skin (2). It is documented that coronary heart disease (CHD) is the major cause of mortality across the globe and the fat deposition in blood vessels predisposes the individuals towards this morbidity (3). The hyperlipidaemia does not show any symptoms however, some signs of the ailment are identified during a clinical examination which include, atherosclerotic plaques in the arteries, chest pain, glucose intolerance, heart attacks, pimple-like lesions on the body, higher rate of obesity along with liver and

spleen enlargement (4). It is stated that "the chronic heart disease is associated with increased levels of total cholesterol, triglycerides and LDL cholesterol and low level of HDL" (5).The risk factors for hyperlipidaemia include decreased physical activity, cigarette smoking, low HDL cholesterol, obesity or overweight, and presence of these ultimately lead to development of diabetes mellitus and hypertension the documented triage of metabolic syndrome (1).

The drugs used for the treatment of hyperlipidaemia includes statins, niacin analogues, and bile acid-binding resins, and fibrates. However, it has been documented that the current drugs therapy is more inclined to decreased serum lipid levels in hyperlipidaemic patients and predisposes the patients to various drug related adverse reactions, along with that there are also chance of development of drug resistance (6). Considering this utilization of herbs has increased in recent times additionally, lower side effect profile and better tolerability has further endorsed their utilization for antihyperlipidemic use (7). Despite, multi-drug treatment i.e. combining allopathic medicines and medicinal plants, have come into lime light but, the drug herb interaction has limited the use of these combination therefore, exploring these affects is of utmost importance for the management of hyperlipidaemia. During the past few years, the studies on the antihyperlipidemic effect of medicinal plants have gained much advancement to some extent, but some limitations are also present. It has been reported in various randomized clinical trials, that different plants show equal efficacy as that of the marketed drugs but mechanism of action behind there antihyperlipidemic activity is still explored (7).

Current literature has highlighted various herbal agents for the management of the lipid profile among them Allium sativum (garlic) has shown its antihyperlipidemic effects by inhibiting HMG CoA reductase (8), Terminalia arjuna shows cardioprotective effects (9), Cinnamomum verum (cinnamon) activates AMPK to decrease the lipogenesis (10), Trigonella foenumgraecum (fenugreek) increase faecal bile excretion (11), and Zingiber officinale (ginger) accelerates cholesterol clearance by upregulating CYP7A1 enzyme (12). It is documented that Allium sativum (garlic), Terminalia arjuna, Cinnamomum verum (cinnamon), Trigonella foenum-graecum (fenugreek), and Zingiber officinale (ginger) have shown antihyperlipidemic activity by various mechanisms. All the known effects of these herbal agents are reported individually however, combining these together may give a multitargeted synergistic regimen which can provide a multidimensional affect against hyperlipidaemia. Therefore, the current study aims to evaluate antihyperlipidemic activity of these herbal agents when used in combination.

METHODOLOGY

It was an open labelled parallel arms clinical trial conducted at Department of Pharmacology, HCMD in collaboration with Hamdard University Hospital, National Medical Center and Amna Ibrahim Unani Clinic. The sample size was calculated to be 200. Patients ageing between 35–65 years of any gender, having central obesity (waist circumference with ethnicity specific), triglycerides ≥ 150 mg/dl (1.7 mmol/L), HDL < 40 m/dl (1.03 mmol/L) in males and < 50 mg/dl (1.29 mmol/L) in females and systolic BP ≥ 130 or diastolic BP ≥ 85 mmhg were included. The exclusion criteria was lactating and pregnant females, patients with other chronic diseases, patients engaged in exercises, having history of MI, CABG, unstable angina, or heart failure and a reason that substantiates the use of drugs in the research.

The sample was distributed in two groups based on the drug adminstration. Group A included 100 patients who were prescribed Tab. Telmisartan 80 mg and Tab. Rosuvastatin 10 mg once daily for 12 weeks. Patients of group B received a herbal formulation containing Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, and Zingiber officinale at a dose of 500 mg per capsule (100mg each herb), taken daily for two times for a period of 12 weeks. BMI calculation, Waist/Hip Ratio, Blood pressure (Systolic and Diastolic), Lipid profile (Total Cholesterol, HDL, LDL, TGs), Alanine Transaminase (ALT) and Aspartate aminotransferase (AST) were measured before and after the intervention. The written informed consent was taken, and the study was approved from IRB of the institute. Data was analyzed using SPSS version 27. Student sample t test was used to compare the groups at the end of the trial.

RESULTS

There were 200 participants in the study, group wise gender distribution of the participants is shown in table 1. The mean age of the study participants in group A was 53.96 and group B was 52.42 years ($p = 0.312$). The comparison of systolic and diastolic blood pressure from day 0 to day 90 showed an insignificant difference between the herbal treatment and allopathic medicine treated group table 2 shows the comparison of systolic and diastolic blood pressure between group A and Group B. The evaluation of serum cholesterol (SC), high density lipoprotein (HDL), low density lipoprotein (LDL), and triglycerides (TGD) across groups over 3 month period revealed no significant difference between the groups. The SC, LDL, and TGD levels decreased to normal range and HDL levels increased however the potency of both the treatment methods remains equally potential in managing lipid profile (table 3). The BMI and WHR showed a significant decrease in herbal treatment group when compared to allopathic group (table 4). Lastly the liver profile markers ALT and AST also showed significant decrease in herbal treatment group ensuring its safety concerns when compared to conventional therapy.

Table. 1 Group wise gender distribution of the participants

	Gender		Total
	Male	Female	
Group A	45	55	100
Group B	37	63	100
Total	100	100	200

Table 2. Difference in systolic blood pressure (SBP) and Diastolic blood pressure (DBP) at 3 months time interval

Outcome Variable	Group statistics		p-value
	Groups	Mean ± Std. Deviation	
SBP (Day 0)	Group A	152.71 ± 9.19	0.210
	Group B	154.14 ± 8.64	
SBP (Day 30)	Group A	135.37± 8.71	0.111
	Group B	136.40 ± 10.29	
SBP (Day 60)	Group A	124.54 ± 8.02	0.091
	Group B	126.20 ± 6.54	
SBP (Day 90)	Group A	121.05 ± 6.28	0.071
	Group B	124 ± 7.17	
DBP (Day 0)	Group A	94.71 ± 7.53	0.069
	Group B	94.34 ± 6.69	
DBP (Day 30)	Group A	85.84± 6.04	0.062
	Group B	82.81 ± 7.15	
DBP (Day 60)	Group A	78.6 ± 5.13	0.099*
	Group B	81.65 ± 6.16	
DBP (Day 90)	Group A	74.67 ± 5.02	0.050
	Group B	72.65 ± 7.05	

Table 3. Difference in Serum Cholesterol (SC), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), and Triglycerides (TGD)

	Group statistics		p-value
	Groups	Mean ± Std. Deviation	
SC (Day 0)	Group A	247.93 ±31.13	0.088
	Group B	248.09 ± 29.45	
SC (Day 30)	Group A	228.09 ±28.64	0.062
	Group B	230.65 ±27.98	
SC (Day 60)	Group A	212.12 ± 23.12	0.051
	Group B	212.19 ±22.37	
SC (Day 90)	Group A	188.85 ±22.91	0.102
	Group B	190.30± 25.52	
HDL (Day 0)	Group A	32.80± 4.14	0.078
	Group B	33.76±7.97	
HDL (Day 30)	Group A	40.82 ± 5.43	0.077
	Group B	38.15 ±4.68	
HDL (Day 60)	Group A	46.54 ± 4.82	0.074
	Group B	47.88 ± 5.38	
HDL (Day 90)	Group A	58.70 ± 8.75	0.055
	Group B	59.66 ± 6.34	
LDL (Day 0)	Group A	127.96± 19.09	0.071
	Group B	128.12± 20.95	
LDL (Day 30)	Group A	112.01 ± 17.18	0.221
	Group B	110.99 ± 20.11	
LDL (Day 60)	Group A	92.97 ± 14.26	0.191
	Group B	91.15 ± 18.50	
LDL (Day 90)	Group A	84.60 ± 12.97	0.521
	Group B	85.21 ± 16.55	
TGD (Day 0)	Group A	252.98 ± 78.29	0.099
	Group B	258.61 ± 86.91	

TGD (Day 30)	Group A	176.81 ± 59.42	0.000*
	Group B	172.57 ± 76.48	
TGD (Day 60)	Group A	126.26 ± 47.89	0.003*
	Group B	128.71 ± 65.77	
TGD (Day 90)	Group A	119.95 ± 45.49	0.321
	Group B	121.71 ± 31.92	

Table 4. The Body Mass Index (BMI), Waist Hip Ratio (WHR) of patients

Outcome Variable	Group statistics		p-value
	Groups	Mean ± Std. Deviation	
BMI (Day 0)	Group A	30.02±3.47	0.062
	Group B	30.12 ± 2.91	
BMI (Day 30)	Group A	29.42 ± 3.40	0.001*
	Group B	28.24 ± 3.26	
BMI (Day 60)	Group A	28.12 ±3.21	0.001*
	Group B	27.54 ± 3.62	
BMI (Day 90)	Group A	27.25 ± 3.15	0.022*
	Group B	26.32 ±3.04	
WHR (Day 0)	Group A	0.99 ±0.09	0.10
	Group B	1.20 ± 0.12	
WHR (Day 30)	Group A	0.97 ±0.09	0.001*
	Group B	0.93±0.02	
WHR (Day 60)	Group A	0.92 ±0.093	0.001*
	Group B	0.88 ± 0.33	
WHR (Day 90)	Group A	0.90±0.09	0.001*
	Group B	0.86 ±0.08	

Table 5. Comparison of Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Serum Creatinine (SCR) across groups over 3-month period

Variable	Group statistics		p-value
	Groups	Mean ± Std. Deviation	
ALT (Day 0)	Group A	36.23 ± 24.93	0.055
	Group B	37 ± 26.68	
ALT (Day 30)	Group A	30.62 ±21.07	0.000*
	Group B	28.98 ±19.94	
ALT (Day 60)	Group A	22.66±15.59	0.000*
	Group B	19.76±9.71	
ALT (Day 90)	Group A	18.17 ± 8.93	0.000*
	Group B	13.56 ± 9.33	
AST (Day 0)	Group A	32.85± 17.15	0.088
	Group B	33.48± 18.531	
AST (Day 30)	Group A	29.09 ± 15.19	0.000*
	Group B	25.62 ±13.38	
AST (Day 60)	Group A	23.13 ± 12.08	0.000*
	Group B	19.51± 8.96	
AST (Day 90)	Group A	18.33 ± 8.42	0.001*
	Group B	15.96 ± 8.33	

DISCUSSION

Managing the hypertension and hyperlipidemia has remained challenging and a corner stone for improving the cardiac health and prevention of cardiovascular risk. The standard pharmacological interventions such as administrating combination of long-acting angiotensin II receptor blocker (ARBs) telmisartan, and HMG-co reductase inhibitor rosuvastatin provide well established and documented hemodynamic and antiatherogenic benefits (13, 14). Whereas, long term administration of these drugs posses the patients to wards risks of development of side effects of these medicine predominantly statin induced abnormal liver enzymatic profile and muscle weakness (15). The current study compared polyherbal combination of Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, and Zingiber officinale with standard drug regimen and identified the therapeutic comparability between the groups in terms of therapeutic efficacy and safety profile.

The applied treatment modalities showed a progressive as well as statistically significant reduction in systolic and diastolic profile over the period of 90 days. The AT1 receptor blocker telmisartan suppress angiotensin II mediated vasoconstriction and aldosterone release hence contributes in reduction of BP (16). Comparatively, the polyherbal formulated group achieved the therapeutic equivalence may be by the presence of various bio active compounds of the different herbal agents. It is documented that Terminalia arjuna possess arjunolic acid and triterpenoids which enhances the vascular endothelial nitric oxide synthase expression and facilitates in endothelium dependent vasodilation (17). Additionally, the Allium sativum has organosulfer constituent vinyldithiines that yield hydrogen sulfide which leads to hyperpolarization of smooth muscles and ultimately leads to muscle relaxation due to which blood pressure may be decreased (18).

The employed therapeutic strategies showed no differences in managing lipid profile. The decrease in serum cholesterol, LDL levels and TRD and increase in HDL levels was not significantly difference in both the group throughout the study duration. The polyherbal compounds have been reported to modulate various lipid metabolism pathways that could be the reason of equal efficacy of both the treatments (19). It is reported that garlic and cinnamon have been reported to inhibit HMG-CoA reductase like rosuvastatin. HMG-CoA reductase is the rate limiting enzyme responsible for the hepatic mevalonate biosynthesis that causes hepatic LDL receptor upregulation and clearance of circulating LDL (20). Furthermore, cinnamaldehyde has been documented to activate AMP activated kinase (AMPK), which phosphorylates and inhibits the sterol regulatory element-binding protein 1c (SREBP-1c) and HMG-CoA reductase ultimately reduce the de novo lipogenesis (21). Fenugreek and ginger promote bile acid excretion by modulating CYP7A1. Briefly, galactomannan dietary fibers of fenugreek bind to intestinal bile acids and prevent recirculation of these acids ultimately facilitate conversion of cholesterol to bile acid by CYP7A1 upregulation. Arjuna and ginger provide antioxidants to prevent the foam cell formation and macrophage uptake in the arterial intima hence provide cardioprotective effects (22).

In the current trial the BMI and WHR was shown to be significantly decreased over the 12 weeks intervention. This pronounced reduction in both of these anthropometric measurements may be attributed to the synergistic bioactivity of 4-hydroxoisolucien (a phytoconstituent of fenugreek) and cinnamaldehyde which stimulates insulin sensitivity and GLUT4 translocations in the skeletal muscles (23). The increased insulin signaling downregulates the hormone sensitive lipase activity in visceral adipose tissue that restricts the excessive free fatty acid influx in to the blood stream and modulate the visceral fat accumulation (24). The polyherbal formulation showed a favorable safety profile when compared he rosuvastatin. The low dose rosuvastatin is well tolerated whereas, due to alteration in membrane permeability of hepatic cell during mevalonate suppression the statins are reported to be responsible for increasing the hepatocellular transaminase. However, the reduction in liver enzymes in polyherbal group highlights the hepatoprotective effect of these herbs (20, 25).

The comparable lipid lowering and antihypertensive activity observed in the current study aligns with the studies reported earlier for the effectiveness of these compounds individually. In a systematic review garlic powder has been reported responsible for reduction in TC and LDL-C levels which was comparable with the statins (26), additionally, fenugreek seed extract and cinnamon extract are documented to reduce fasting plasma glucose, TC, and TGD levels through enhanced insulin activity and biliary fat excretion (27). Contrary to current finding few trials have also documented that the herbs (ginger and garlic) when used individually, showed inferior efficacy when compared to high potency statins such as atorvastatin and rosuvastatin (28). These differences in the results when used individually and in combination shows advantage of the current study that when targeted by multiple pathways through different herbs the at low doses shows a comparable efficacy as that of conventionally available drug. Due to financial constraints a small sample size was evaluated for the study along with that diabetic patients were not included to identify the effects of this poly formulation on diabetic profile.

Conclusion

The combination of Allium sativum, Cinnamomum verum, Terminalia arjuna, Fenugreek, and Zingiber officinale showed comparable effects in managing the lipid profile of the patients when compared to rosuvastatin. The herbal combination showed a superior activity in decreasing BMI and waist hip ratio of the patients.

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